THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH WITH OPTIONAL PROCEDURES

A Phase I/II Study of Pembrolizumab (MK-3475) in Combination with Romidepsin in Patients with Relapsed or Refractory Peripheral T-Cell Lymphoma
2017-0272

Study Chair: Swaminathan P. Iyer

Participant's Name _____ Medical Record Number _____

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB – a committee that reviews research studies).

STUDY SUMMARY

The goal of this clinical research study is to learn if it is safe to give pembrolizumab in combination with romidepsin to patients with peripheral T-cell lymphoma or cutaneous T-cell lymphoma. Researchers also want to learn if the study drug combination can help to control the disease.

This is an investigational study. Pembrolizumab is FDA approved and commercially available for the treatment of certain types of melanoma. Romidepsin is FDA approved and commercially available for the treatment of peripheral T-cell lymphoma and cutaneous T-cell lymphoma. The use of these drugs in combination with each other is investigational.

The study doctor can explain how pembrolizumab and romidepsin are designed to work.

The study drugs may help to control the disease. Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. If you take part in this study, you may experience side effects, some of which may be severe or fatal.

You can read a list of potential side effects below in the Possible Risks section of this consent.

You may continue taking the study drugs for up to 36 cycles, as long as the doctor thinks it is in your best interest.

Pembrolizumab will be provided at no cost to you while you are on study. You and/or your insurance provider will be responsible for the cost of romidepsin.

You may choose not to take part in this study. Instead of taking part in this study, you may choose to receive romidepsin without taking part in this study. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for cancer at all. In all cases, you will receive appropriate medical care, including treatment for pain and other symptoms of cancer.

1. STUDY DETAILS

Screening Tests

Signing this consent form does not mean that you will be able to take part in this study. The following screening tests will be to help the doctor decide if you are eligible:

- You will have a physical exam.
- Blood (about 3 teaspoons) will be drawn for routine tests and for tests of your thyroid function.
- Urine will be collected for routine tests.
- You will have an EKG to check your heart function.
- Blood (about 1 teaspoon) will be drawn for research testing. In this consent form, "research testing" may include biomarker testing (including genetic biomarkers) and cytokine testing. Biomarkers are found in the blood/tissue and may be related to your reaction to the study drug. Cytokines are proteins that may affect your immune system. This research testing may help researchers learn which patients are most likely to be affected by the study drugs.
- Leftover tumor tissue from a previous biopsy will be collected to confirm your diagnosis. If you do not have leftover tumor tissue available, you will have a core needle biopsy. To perform a core biopsy, a sample of tissue is removed using a hollow core needle that has a cutting edge.
- You will have CT and/or PET/CT scans to check the status of the disease. If the doctor thinks it is needed, you may have other types of imaging scans to check the status of the disease. This will be discussed with you.
- You may have a bone marrow aspirate and/or biopsy to check the status of the disease. To collect a bone marrow aspirate/biopsy, an area of the hip or

other site is numbed with anesthetic, and a small amount of bone marrow and bone is withdrawn through a large needle.

- If you can become pregnant, part of the above routine blood sample or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

The study doctor will discuss the screening test results with you. If the screening tests show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups

If you are found to be eligible to take part in this study, you will be assigned to a study group based on when you join this study. Up to 3 groups of up to 6 participants will be enrolled in Phase 1 of the study, and up to 21 participants will be enrolled in Phase 2.

If you are enrolled in Phase 1, the dose of romidepsin you receive will depend on when you join this study. The first group of participants will receive the highest dose level of romidepsin. A second group will receive a lower dose of romidepsin than the group before it, if intolerable side effects are seen. A third group will receive an even lower dose if there are still intolerable side effects.

If you are enrolled in Phase 2, you will receive romidepsin at the highest dose that was tolerated in Phase 1.

All participants will receive the same dose level of pembrolizumab.

Up to 39 participants will be enrolled in this study. All will take part at MD Anderson.

Study Drug Administration

You will receive the study drugs in 21-day study cycles. On Day 1 of each cycle, romidepsin will be given first, followed by pembrolizumab. Romidepsin will be given by vein over about 4 hours on Days 1 and 8 of every cycle. You will receive pembrolizumab by vein over about 30 minutes after romidepsin on Day 1 of each cycle.

If you are in Phase 2, you will not receive romidepsin on Day 1 of Cycle 1.

You will no longer be able to take the study drug if the disease gets worse, if intolerable side effects occur, or if you are unable to follow study directions.

Your participation on the study will be over after the follow-up visits.

Study Visits

You will have study visits on **Days 1 and 8 of Cycle 1.** You will then have study visits on **Days 1 and 8 of Cycles 2 and 3.** After that, you will only have study visits on **Day 1 of Cycles 4 and beyond.** At each of these visits:

- You will have a physical exam.
- Blood (1 tablespoon) will be drawn for routine tests.

- On **Day 1 of Cycle 1 and within 72 hours before Day 1 of each cycle**, if you can become pregnant, part of the above routine blood sample or urine will be collected for a pregnancy test. To take part in this study, you must not be pregnant.

At some of these visits, additional tests will be performed:

- On **Day 1 of every cycle that you receive romidepsin**, you will have an EKG within 6 hours before you receive romidepsin.
- On **Day 1 of Cycles 1-3, Day 8 of Cycles 1 and 2, and Day 15 of Cycle 1**, blood (about 1 teaspoon) will be drawn for research tests.
- On **Day 1 of Cycle 2 and every 2 cycles after that**, blood (about 1 tablespoon) will be drawn for thyroid function tests.
- On **Day 1 of Cycle 4 and every 3 cycles after that**, you will have the same imaging scans (such as CTs or PET/CTs) you had at screening to check the status of the disease.

End-of-Dosing Visits

When you stop receiving the study drugs, blood (about 1 tablespoon) will be drawn for routine tests and thyroid function tests. You will have these blood tests again 30 days later.

If your treatment stops because the disease is quickly getting worse, some of the tests and scans above will be repeated.

Follow-Up

Every 12 weeks after the second end-of-dosing visit:

- Blood (about 1 tablespoon) will be drawn for routine tests and thyroid function tests.
- You will have the same imaging scans (such as CTs or PET/CTs) you had at screening to check the status of the disease.

You will also be called every 12 weeks to be asked about your health. This call should last about 15 minutes.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. These side effects will vary from person to person. The more commonly occurring side effects are listed in this form, as are rare but serious side effects. You should discuss these with the study doctor. You may also want to ask about uncommon side effects that have been observed in small numbers of patients but are not listed in this form. Many side effects go away shortly after treatment is stopped, but in some cases side effects may be serious, long-lasting or permanent, and may even result in hospitalization and/or death.

Tell the study staff about any side effects you may have, even if you do not think they are related to the treatment/procedures.

Romidepsin and pembrolizumab each may cause low blood cell counts (red blood cells, platelets, and/or white blood cells):

- A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
- A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion.
- A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and difficulty breathing.

Romidepsin Side Effects

Common (occurring in more than 20% of patients)

• abnormal EKG • low blood pressure (possible dizziness/fainting) • fatigue • fever • headache • skin rash and/or itching • shedding and scaling of the skin (possible fatal loss of bodily fluids) • high blood sugar (possible diabetes)	• abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure) • nausea • loss of appetite • vomiting • abnormal taste • constipation/diarrhea	• low blood cell counts (white, red, platelets) • abnormal liver test (possible liver damage and/or yellowing of the skin and/or eyes) • weakness • high blood levels of uric acid (possible painful joints and/or kidney failure) • cough • difficulty breathing • infection

Occasional (occurring in 3-20% of patients)

• swelling (arm/leg) • fast heartbeat	• chills • weight loss • abdominal pain	• mouth blisters/sores (possible difficulty swallowing)

Exact frequency unknown but occurring in fewer than 10% of patients

• chest pain • irregular heartbeat • blood clots in a vein (possible pain, swelling, and/or redness) • fainting	• lung inflammation (possible difficulty breathing) • blockage in the lung (possible pain and/or shortness of breath)	• low oxygen level in the blood (possible lightheadedness) • allergic reaction • severe life-threatening infection (possible low

• dehydration		blood pressure, kidney failure, and/or heart failure)

Rare but serious (occurring in fewer than 3% of patients)

• heart failure • shock caused by heart damage • decreased blood supply to the heart	• bacteria in the blood • kidney failure • failure of multiple organs	• breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)

Romidepsin also may cause reactivation of hepatitis B (liver damage) and/or reactivation of the Epstein-Barr virus (EBV) with possible liver failure. EBV reactivation is rare, but it is not known how often hepatitis B reactivation may occur.

Pembrolizumab Side Effects

Common (occurring in more than 20% of patients)

• fatigue • fever • skin rash and/or itching • abnormal salts, minerals, and/or acids in the blood (possible weakness, swelling, fatigue, low blood pressure, organ failure, heart problems, changes in mental status, and/or seizure)	• high blood sugar (possible diabetes) • high blood levels of fat (possible heart disease and/or stroke) • loss of appetite • nausea • constipation • low blood cell count (white/red)	• abnormal liver test (possible liver damage) • pain • abnormal kidney test (possible kidney damage) • cough

Occasional (occurring in 3-20% of patients)

• swelling (face/arm/leg) • headache • confusion • underactive thyroid gland (possible weight gain, heart failure, and/or	• weight loss • diarrhea • vomiting • weakness • abdominal pain • blood in urine	• nerve damage (possible numbness, pain, and/or loss of motor function) • difficulty breathing (possibly due to lung

constipation) • overactive thyroid gland (possible weight loss, diarrhea, mood swings, difficulty sleeping, heart rate changes, and/or sweating)	• abnormal liver tests (possible yellowing of the skin and/or eyes)	inflammation) • infusion reaction (possible dizziness, low blood pressure, nausea, pain, and/or difficulty breathing)

Rare but serious (occurring in fewer than 3% of patients)

• heart inflammation • blood vessel inflammation (possible bleeding and/or bruising) • seizure • immune system damage to the nervous system (causing numbness and/or paralysis) • spinal cord inflammation (possible pain, weakness, loss of feeling or movement, and/or paralysis) • brain inflammation (possible paralysis and/or coma) • shedding, scaling and/or inflammation of the skin (possible fatal loss of bodily fluids) • large skin blisters • very severe blistering skin disease (loss of large portion of skin and/or ulcers of the skin and digestive tract)	• hormonal deficiency that affects the body's ability to control blood pressure and react to stress • pituitary gland inflammation (possible headaches) • decreased production of adrenal hormones (possible weakness and/or low blood pressure) • inflammation of the thyroid gland (possible tenderness in the neck) • diabetes requiring insulin • severe high blood sugar due to uncontrolled diabetes • inflammation of the pancreas (possible abdominal pain) • anemia due to destruction of red blood cells • liver damage (hepatitis)	• inflammation inside the eye (possible vision problems) • kidney inflammation (possible kidney damage/failure) • kidney failure • build-up of fluid around the lungs • immune response that causes the body to attack itself (possible organ damage) • multi-organ disease causing lesions, most often in the lungs (sarcoidosis) • immune response (causing muscle weakness) • severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure) • Vogt Koyanagi Harada syndrome -- pigmented tissue (possible eye pain/swelling and changes in vision, hearing loss, and/or white patches on the skin)

If you have a stem cell transplant from a donor after you receive pembrolizumab, you may have an increased risk of complications, such as severe graft-versus-host

disease (when transplanted donor tissue attacks the recipient's organs such as skin, liver, and/or intestines) and/or clotting of blood within the liver. Deaths have been reported in patients who received a stem cell transplant from a donor after pembrolizumab therapy. If you decide to receive a stem cell transplant from a donor, please tell your transplant doctor that you received pembrolizumab in the past.

If you have any type of organ transplant including an allogeneic bone marrow transplant, pembrolizumab may increase your risk for the following:

- the transplant to be rejected by your body,
- graft vs. host disease
- fever (which may need steroids to lower)
- clots in the veins of the liver and other immune reactions against different organs of the body.

Pembrolizumab may increase your risk of transplant-related death.

Pembrolizumab works by boosting the immune system. This may cause unknown side effects resulting from your immune system attacking your organs. This may cause inflammation and inflammation-related side effects in any organ or tissue.

Using the study drugs together may cause side effects that are not seen when each is given alone. The study drug combination may also increase the frequency and/or severity of the side effects listed above.

Other Risks

Blood draws may cause pain, bleeding, and/or bruising. You may faint and/or develop an infection with redness and irritation of the vein at the site where blood is drawn. Frequent blood collection may cause anemia (low red blood cell count), which may create a need for blood transfusions.

Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

EKGs may cause discomfort while lying on the exam table, and the tape on the EKG pads may cause skin irritation.

CT scans send x-rays through the body at many different angles. You will be exposed to a small dose of radiation. All radiation adds up over a lifetime and may increase the risk of new cancer forming. Some people may feel “closed in” while lying in the scanner. However, the scanner is open at both ends, and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or radiology technicians will give comfort, or the scanning will be stopped. Solution may also be given by vein to make the x-ray pictures more accurate. This may cause an uncomfortable feeling of warmth, nausea, and/or severe allergic reactions. The solution injection may also cause pain, bleeding, bruising, hives, and/or itching.

A **PET scan** may cause you to feel "closed in" while lying in the scanner. However, the scanner is open at both ends and an intercom allows you to talk with doctors and staff. If you feel ill or anxious during scanning, doctors and/or technicians will give comfort or the scanning will be stopped.
PET scan exposes your body to radiation. The radioactive solution does not remain in your system for a long period of time. However, you should wait 2 hours before holding an infant or getting close to a pregnant woman to avoid exposing them to radiation. You should drink fluids after the scan to help remove the solution from your system.

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets and will continue to be stored securely after the study.

This study may involve unpredictable risks to the participants.

Pregnancy Related Risks
Taking part in this study can result in risks to an unborn or breastfeeding baby, so you should not become pregnant, breastfeed a baby, or father a child while on this study. You must use birth control during the study if you are sexually active.

Birth Control Specifications: If you can become pregnant or father a child, you must agree to avoid becoming pregnant or impregnating a partner while receiving study drug and for 120 days after the last dose of study drug.

Acceptable methods include intrauterine device (IUD), vasectomy, or implanted birth control rod.

You may also use 2 of the following methods:

- diaphragm with spermicide (cannot be used with cervical cap/spermicide)
- cervical cap with spermicide (only for women who have not had children)
- birth control sponge (only for women who have not had children)
- male condom or female condom (cannot be used together)
- hormonal birth control methods such as the pill (estrogen/progestin pill or progestin-only pill), skin patch, vaginal ring, or injection

Males: Tell the doctor right away if your partner becomes pregnant or suspects pregnancy.

Females: If you are pregnant, you will not be enrolled on this study. If you become pregnant or suspect that you are pregnant, you must tell your doctor right away.

Getting pregnant will result in your removal from this study.

OPTIONAL PROCEDURES FOR THE STUDY

Optional Procedure #1: If you agree, you will have up to 2 additional core needle biopsies. To perform a core biopsy, a sample of tissue is removed using a hollow core needle that has a cutting edge. The first would be collected on Day 15 of Cycle 1, and the second would be collected if at any time the disease gets worse. These biopsies will be used to compare to the sample taken at screening and for biomarker testing (including genetic biomarkers).

Optional Procedure #2: If you agree, leftover blood and/or tissue from study testing will be stored indefinitely (forever) in a research bank at MD Anderson for use in future research related to cancer.

Before your samples can be used for research, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson. The IRB is a committee of doctors, researchers, and community members. The IRB is responsible for protecting study participants and making sure all research is safe and ethical.

Your samples will be given a code number. Only individuals with IRB permission and designated bank staff will have access to the code numbers and be able to link the samples to you. This is to allow medical data related to the samples to be updated as needed. Additionally, if needed for certain types of research in the future and if the IRB approves, the bank staff and approved research staff will be able to link your samples back to you.

There are no benefits to you for taking part in the optional procedures. Future patients may benefit from what is learned. You may stop taking part at any time. There will be no cost to you for taking part in the optional procedures.

Optional Procedure Risks:
Having **biopsies** performed may cause pain, bruising, bleeding, redness, low blood pressure, swelling, and/or infection at the site of the biopsies. An allergic reaction to the anesthetic may occur. A scar may form at the biopsy site.

MD Anderson and others can learn about cancer and other diseases from your banked samples. In the future, people who may do research with these samples may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your

privacy, but cannot guarantee complete privacy. Sometimes your samples may be used for genetic research about diseases that are passed on in families.

If you withdraw your consent to the storage of leftover samples in the tissue bank, then they will no longer be collected for storage. Any of your samples that remain in the tissue bank will no longer be used for research and will be destroyed.

However, if any of your de-identified samples were already released for research purposes before you withdrew consent, MD Anderson will not be able to destroy them.

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

CONSENT/PERMISSION/AUTHORIZATION FOR OPTIONAL PROCEDURES

Circle your choice of "yes" or "no" for each of the following optional procedures:

Optional Procedure #1: Do you agree to have biopsies on Day 15 of Cycle 1 and then at any time the disease appears to get worse?

YES NO

Optional Procedure #2: Do you agree to allow leftover blood and/or tissue to be stored in a research bank at MD Anderson for use in future research related to cancer?

YES NO

3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson or Merck for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However,

your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

Samples that are collected from you in this study may be used for the development of treatments, devices, new drugs, or patentable procedures that may result in commercial profit.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the study chair (Dr. Swaminathan P. Iyer, at 713-792-2860) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

   If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the study doctor can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, Merck, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.

7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

8. MD Anderson may benefit from your participation and/or what is learned in this study.

9. This study is sponsored and/or supported by: Merck.

10. In a medical emergency, you may be cared for by someone who has a financial interest with the study sponsor(s)/supporter. If you have any questions about this, you may call the IRB at 713-792-6477.

Future Research

Data
Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and Merck, and/or shared with other researchers and/or institutions for use in future research.

Samples
Samples (such as blood and/or tissue) are being collected from you as part of this study. Researchers at MD Anderson may use any leftover material that is stored at MD Anderson in future research. Leftover material stored by Merck may be used in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data and/or research samples. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data or research samples are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data and/or research samples can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data and/or samples.

Genetic Research
Research samples collected from you as part of this study will be used for genetic research, which may include whole genome sequencing. Whole genome sequencing is a type of testing in which researchers study your entire genetic makeup (DNA). This may help researchers learn how changes in the ordering of genes may affect a disease or response to treatment.

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most

employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research when deciding to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this federal law prohibit discrimination based on an already known genetic disease or disorder.

Outside Care
Part of your care may be provided outside of MD Anderson by your home doctor(s).

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
   - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
   - The IRB and officials of MD Anderson
   - Merck, who is a sponsor or supporter of this study, and/or any future sponsors/supporters of the study
   - any future sponsors and/or licensees of the study technology
   - Study monitors and auditors who verify the accuracy of the information
   - Individuals who put all the study information together in report form

   Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

   The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.

C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

E. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol 2017-0272.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR) DATE

PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION